DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 6, 2015

Nanning Baolai Medical Instruments Co., Ltd.
c/o Mr. Mike Gu
Osmunda Medical Device Service Group
Level 7, Jin Gui Business Center
982 Cunyun Road, Baiyun District
Guangzhou, Guangdong 510420
CHINA

Re: K140233
Trade/Device Name: Ultrasonic scaler P7
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic scaler
Regulatory Class: II
Product Code: ELC
Dated: February 28, 2014
Received: March 3, 2015

Dear Mr. Gu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140233

Device Name
Ultrasonic scaler P 7

Indications for Use *(Describe)*

The ultrasonic scaler is intended to:

1. Remove supra and sub gingival calculus deposits and stain from the teeth;
2. Carry out periodontal pocket lavage with simultaneous ultrasonic tip movement;
3. Clean and irrigate root canals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Submitter:	Nanning Baolai Medical Instruments Co., Ltd., 7th Floor, General Building, Hetai Sci. &Tech. Park, No.9 Gaoxin 4th RD., Nanning ,Guangxi, 530007, China
Primary Contact Person:	Mike Gu Regulatory Affairs Manager Osmunda Medical Device Consulting Co., Ltd. (+86)-020-62321333 (+86)-020-86330253
Secondary Contact Person:	Wanqing Bi Deputy Manager Nanning Baolai Medical Instrument Co., Ltd. 0086-771-3815998 0086-771-3217883
Device: Trade Name:	Ultrasonic scaler P7
Common/Usual Name:	Ultrasonic scaler
Classification Names:	Ultrasonic scaler
Product Code:	ELC
RegulationNumber	21 CFR 872.4850
Date prepared	April 1th, 2015
Number of submission	K140233
Predicate Device(s):	Guilin Woodpecker USD-L ultrasonic scaler, K053555
Device Description:	Ultrasonic scaler employs piezoelectric technology to produce a steady power. It is composed of a control unit housing a generator that produces piezo-electric vibrations. The working instrument for the ultrasonic scaler is the handpiece, which is connected to the control unit via a handpiece cord. A scaling tip specific to a particular procedure is attached to the end of the handpiece. The ultrasonic scaler connects to an external water supply and delivers water via connected handpiece.
Intended Use:	The ultrasonic scaler is intended to: 1. Remove supra and sub gingival calculus deposits and stain from the teeth; 2. Carry out periodontal pocket lavage with simultaneous ultrasonic tip movement; 3. Clean and irrigate root canals.
Technology:	The ultrasonic scaler is powered by the piezoelectric technology,

which is also employed by the predicate device. The electric power is transduced into high-frequency vibration via an ultrasonic transducer.

The working instrument for both the proposed and predicate devices is the handpiece, which is connected to the control unit via a handpiece cord. Both the proposed and predicate ultrasonic scalers connect to an external water supply and deliver water via the handpiece.

Determination of Substantial Equivalence:

The ultrasonic scaler and its predicate device :

- have the same intended use;
- both employ piezoelectric technology and produce ultrasonic vibrations at a frequency of 28kHz±3kHz;
- Have similar main components, i.e. control unit, handpiece cord, handpiece and detachable scaling tips.

Compared to the predicate device, most of their specifications are identical except that the handpiece of the proposed ultrasonic scaler has a metal shell made from aluminum alloy rather than the plastic material used by the predicate device. The difference does not affect the safety of the proposed device as a biocompatibility testing aiming to the handpiece metal shell was conducted and result pass.

Summary of Non-Clinical Tests:

Electrical safety tests according to IEC 60601-1: 2005+CORR. 1 (2006)+CORR. 2 (2007) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;

Electromagnetic Compatibility Test according to IEC 60601-1-2:2007: General requirement for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests;

Bench testing according to IEC 61205:1993 Ultrasonics-Dental descaler systems-Measurement and declaration of the output characteristics.

Biocompatibility testing according to ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity and ISO 10993-10:2006 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.

	Moist sterilization validation according to AAMI / ANSI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013, (Consolidated Text) Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities
Summary of Clinical Tests:	The subject of this premarket submission, ultrasonic scaler, did not require clinical studies to support substantial equivalence.
Conclusion:	Based on the similarities in intended use, principles of operation, design rationale, test results, and performance, Nanning Baolai Medical Instrument Co., Ltd. considers the ultrasonic scaler to be substantially equivalent to the predicate device USD-L ultrasonic scaler.